

ONE HUNDRED SIXTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

January 16, 2020

Mr. Robert R. Redfield, M.D.
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Director Redfield:

We write to request information about the actions that the U.S. Department of Health and Human Services (HHS) has taken to cultivate innovation in Alzheimer's Disease and Alzheimer's Disease-Related Dementias (AD/ADRD or Alzheimer's) research, as well as barriers that stand in the way of discovering treatments or cures for AD/ADRD, and the ways in which Congress can assist in overcoming such barriers. Despite sustained federal involvement, Alzheimer's Disease remains the only top 10 cause of death in the United States that cannot be cured, treated, or slowed.¹

Alzheimer's research and the search for a cure or treatment is, and has been, a priority of HHS for many years. Several HHS agencies, including the National Institute on Aging of the National Institutes of Health (NIH), the Office of the Assistant Secretary for Planning and Evaluation, and the Centers for Disease Control and Prevention (CDC) are responsible for ensuring that various aspects of Alzheimer's research and prevention continue to progress.

The CDC's involvement in Alzheimer's Disease research dates back to 2005, when Congress appropriated funds to create an Alzheimer's Disease segment within CDC's Healthy Aging Program, which was subsequently named The Healthy Brain Initiative.² The Healthy Brain Initiative is a multifaceted approach to cognitive health with several components, including the Public Health Road Map series, surveillance, a communication center, and

¹ Alzheimer's & Dementia 14 (2018) 367 – 439, Alzheimer's Association Report: 2018 Alzheimer's disease facts and figures at 383; *available at* [https://www.alzheimersanddementia.com/article/S1552-5260\(18\)30041-4/pdf](https://www.alzheimersanddementia.com/article/S1552-5260(18)30041-4/pdf).

² U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, The Healthy Brain Initiative: The Public Health Road Map for State and National Partnerships, 2013-2018, Interim Progress Report, *available at* <https://www.cdc.gov/aging/pdf/2013-healthy-brain-initiative-interim-report.pdf>.

resources and publication.³ The goal of the Healthy Brain Initiative is to maintain or improve the cognitive performance of all adults, and while it does not focus solely on Alzheimer's Disease, a reduction in Alzheimer's Disease numbers is a part of its mission.⁴ We are interested in understanding more about the work that CDC has completed with respect to tracking and preventing Alzheimer's Disease. Specifically, we are interested in understanding whether the Healthy Brain Initiative has been successful in combating Alzheimer's Disease, and how CDC uses emerging science to best combat the rise of Alzheimer's Disease.⁵

Congress has been active in promoting a cure or treatment for Alzheimer's, passing multiple pieces of legislation in the last decade. In 2011, Congress passed, and President Obama signed into law, the National Alzheimer's Project Act (NAPA). Through NAPA, Congress charged HHS with establishing the National Alzheimer's Project, which included six objectives regarding diagnosis, treatment, and research for AD/ADRD.⁶ In pursuit of these six objectives, HHS promulgated the National Plan, which established five goals and acted as a road map for both the federal government and the research community.⁷ In 2014, the Alzheimer's Accountability Act was enacted as part of the Fiscal Year (FY) 2015 omnibus appropriations bill.⁸ The Alzheimer's Accountability Act requires the scientists at NIH to submit an annual Alzheimer's research budget proposal directly to Congress—known as the Alzheimer's Bypass Budget—specifying the resources that scientists need to reach the National Alzheimer's Plan goal of preventing and effectively treating AD/ADRD by 2025. In addition, in 2018, the Building Our Largest Dementia (BOLD) Infrastructure for Alzheimer's Act was signed into law.⁹ In an effort to bolster AD/ADRD progress, the BOLD Act further authorized the expansion of activities related to combating AD/ADRD.

Congress has also demonstrated a commitment to AD/ADRD research by appropriating additional funding annually. For FY 2018, Congress approved an additional \$414 million for

³ Centers for Disease Control and Prevention, *Alzheimer's Disease and Health Aging, Healthy Brain Initiative* (last accessed on Dec. 10, 2019), *available at* <https://www.cdc.gov/aging/healthybrain/index.htm>.

⁴ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and the Alzheimer's Association, *The Healthy Brain Initiative: A National Public Health Road Map to Maintaining Cognitive Health*, *available at* <https://www.cdc.gov/aging/pdf/TheHealthyBrainInitiative.pdf>.

⁵ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Alzheimer's Disease and Healthy Aging Program, Healthy Brain Initiative*, *available at* <https://www.cdc.gov/aging/healthybrain/index.htm> (last accessed Oct. 17, 2019).

⁶ The six objectives are: 1) create and maintain a plan to overcome AD/ADRD; 2) coordinate AD/ADRD research across federal agencies; 3) accelerate the development of treatment; 4) improve early diagnosis; 5) decrease racial and ethnic disparities; and 6) coordinate international bodies. National Alzheimer's Project Act, Public Law No. 111-375 (Jan. 4, 2011), *available at* <https://www.congress.gov/bill/111th-congress/senate-bill/3036>.

⁷ The five goals consisted of: 1) prevent and effectively treat AD/ADRD by 2025; 2) optimize care, quality, and efficiency; 3) expand support for people with AD/ADRD and their families; 4) enhance public awareness and engagement; and 5) track progress and drive improvement. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *National Plan to Address Alzheimer's Disease* (Dec. 3, 2018), *available at* <https://aspe.hhs.gov/national-plans-address-alzheimers-disease>.

⁸ Consolidated and Further Continuing Appropriations Act, 2015, Public Law No. 113-235 (Dec. 16, 2014), *available at* <https://www.congress.gov/113/plaws/publ235/PLAW-113publ235.pdf>.

⁹ BOLD Infrastructure for Alzheimer's Act, Public Law No. 115-406 (Dec. 31, 2018), *available at* <https://www.congress.gov/bill/115th-congress/senate-bill/2076>.

Alzheimer's research, bringing the total funding to \$1.828 billion.¹⁰ For FY 2019, Congress directed NIH to reserve \$2.34 billion, an increase of \$425 million from FY 2018.¹¹ Despite legislative action by Congress and increases in research funding, a cure or effective treatment for AD/ADRD remains out of reach.

There are promising developments, however. On October 22, 2019, Biogen announced that it planned to move forward in seeking regulatory approval from the U.S. Food and Drug Administration (FDA) of an investigational treatment for early Alzheimer's disease called aducanumab.¹² If approved by the FDA, this drug "would become the first therapy to reduce the clinical decline of Alzheimer's disease."¹³ While promising, the drug has not been approved by the FDA to date; moreover, according to experts an effective treatment for AD/ADRD will likely include several therapies.¹⁴ Additionally, a recent paper published by researchers notes that a rare genetic mutation may have helped to delay Alzheimer's disease for a woman who was at risk for early onset of Alzheimer's disease.¹⁵ This finding shifts the focus from the amyloid protein to the tau protein, and could inform and lead to new approaches to the treatment of Alzheimer's disease. These are just two examples of potential breakthroughs in the search for treatments and a cure for Alzheimer's disease, but additional research is needed.

Finding a cure or effective treatment for AD/ADRD will continue to require an all-hands-on-deck approach. As the leader in collecting data related to disease, the CDC is familiar with the broad impact of AD/ADRD. A recent CDC study reported AD/ADRD numbers will double by 2060.¹⁶ We request that written answers to the following questions be provided by January 30, 2020. We request you also provide a briefing to staff.

1. In what ways has the Healthy Brain Initiative helped combat the rise of AD/ADRD?
 - a. What components of the Healthy Brain Initiative have proven to be the most effective?
 - b. How has the Healthy Brain Initiative evolved overtime? Specifically, how does the CDC adjust the Healthy Brain Initiative to reflect the most up-to-date AD/ADRD research findings?

¹⁰ Congressional Record (Mar. 22, 2018), vol. 164, no.50—Book III, H2701.

¹¹ H. Rept. 115-952, p. 529.

¹² Biogen, Biogen Plans Regulatory Filing for Aducanumab in Alzheimer's Disease Based on New Analysis of Larger Dataset from Phase 3 Studies (Oct. 22, 2019), *available at* <http://investors.biogen.com/news-releases/news-release-details/biogen-plans-regulatory-filing-aducanumab-alzheimers-disease>.

¹³ *Id.*

¹⁴ Tara Bahrapour, *In surprise turnaround, new analysis finds an Alzheimer's treatment may work*, WASH. POST (Oct. 22, 2019), *available at* https://www.washingtonpost.com/local/social-issues/in-surprise-turnaround-new-analysis-finds-an-alzheimers-treatment-may-work/2019/10/22/cb274fd8-f4e6-11e9-ad8b-85e2aa00b5ce_story.html.

¹⁵ Linda Carroll, *Rare genetic finding may help in search for Alzheimer's therapies*, REUTERS (Nov. 4, 2019), *available at* <https://www.reuters.com/article/us-health-alzheimers-genetics-idUSKBN1XE216>.

¹⁶ The Journal of The Alzheimer's Association, Volume 15, Issue 1 at 17-24, Racial and ethnic estimates of Alzheimer's disease and related dementias in the United States (2015-2060) in adults aged ≥ 65 years (Jan. 2019), *available at* [https://www.alzheimersanddementia.com/article/S1552-5260\(18\)33252-7/fulltext](https://www.alzheimersanddementia.com/article/S1552-5260(18)33252-7/fulltext).

2. Does the CDC review AD/ADRD research in order to better strategize ways to combat AD/ADRD? If so, how often does CDC review AD/ADRD research?
3. Other than the Healthy Brain Initiative, how does the CDC plan to decrease the number of people affected by AD/ADRD in the United States?
4. Based on key research findings of racial disparities in AD/ADRD diagnosis prevalence, what recommendations does CDC have for federal agencies involved in AD/ADRD funding, regulating, guiding, or using research outcomes, to elevate to a national priority the importance of participation by diverse populations in AD/ADRD research studies?
5. Have any strategies been successful in preventing the rise of people affected by AD/ADRD in the United States?
 - a. How long do successful prevention methods need to be in place before AD/ADRD diagnosis numbers improve?
6. What data-based recommendations does CDC have for federal agencies involved in AD/ADRD funding, regulating, guiding, or using research outcomes, to facilitate the creation of national strategy for early assessment and diagnosis?
7. What additional resources are needed by the CDC in order to more effectively stop the rise of AD/ADRD in the United States?

Thank you for your attention to this request. Should you have any questions, and to schedule the requested briefing, please contact Brittany Havens or Diane Cutler of the Republican Committee Staff at (202) 225-3641.

Sincerely,

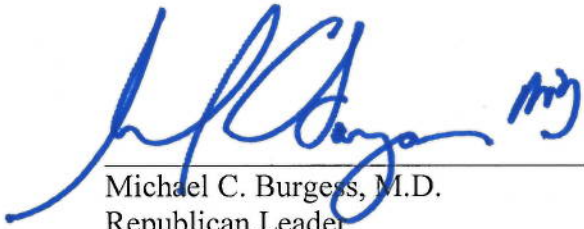


Greg Walden
Republican Leader



Brett Guthrie
Republican Leader
Subcommittee on Oversight
and Investigations

Director Robert R. Redfield, M.D.
January 16, 2020
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A handwritten signature in blue ink, appearing to read "M. Burgess" with a stylized flourish at the end.

Michael C. Burgess, M.D.
Republican Leader
Subcommittee on Health